

## WHAT IS CLAIMED IS:

1. A method for treating a cancer in a patient in need thereof comprising administering to said patient, concurrently or sequentially, a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one signal transduction inhibitor (STI).

2. The method of claim 1, wherein said at least one STI is selected from the group consisting of bcr/abl kinase inhibitors, epidermal growth factor (EGF) receptor inhibitors, her-2/neu receptor inhibitors, farnesyl transferase inhibitors (FTIs), inhibitors of Akt family kinases or the Akt pathway, and cell cycle kinase inhibitors.

3. The method of claim 2, wherein said at least one STI is selected from the group consisting of STI 571, SSI-774, C225, ABX-EGF, trastuzumab, L-744,832, rapamycin, LY294002, flavopiridal, and UNC-01.

4. The method of claim 3, wherein said at least one STI is L-744,832.

5. The method of claim 1, wherein said at least one IDO inhibitor is selected from the group consisting of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-

DL-trp; propenyl-TH-DL-trp, methyl-TH-DL-trp,  
brassilexin, 3-amino-2-naphthoic acid,  $\beta$ -carboline, 3-  
butyl- $\beta$ -carboline, 6-fluoro-3-carbomethoxy- $\beta$ -carboline,  
6-isothiocyanate-3-carbomethoxy- $\beta$ -carboline, 3-propoxy- $\beta$ -  
5 carboline, 3-carboxy- $\beta$ -carboline, 3-carbopropoxy- $\beta$ -  
carboline, and 3-carbo-tert-butoxy- $\beta$ -carboline.

6. The method of claim 5, wherein said at least one  
IDO inhibitor is 1-methyl-tryptophan (1MT).

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7. The method of claim 1, wherein said at least one  
IDO inhibitor and said at least one STI are administered  
concurrently.

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8. The method of claim 1, wherein said at least one  
IDO inhibitor and said at least one STI are administered  
sequentially.

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9. The method of claim 8, wherein said at least one  
IDO inhibitor is administered before said at least one  
STI.

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10. The method of claim 8, wherein said at least  
one STI is administered before said at least one IDO  
inhibitor.

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11. The method of claim 1, wherein said cancer is  
selected from the group consisting of cancers of the  
prostate, colorectum, pancreas, cervix, stomach,  
endometrium, brain, liver, bladder, ovary, testis, head,  
neck, skin (including melanoma and basal carcinoma),  
mesothelial lining, white blood cell (including lymphoma  
and leukemia) esophagus, breast, muscle, connective  
tissue, lung (including small-cell lung carcinoma and

non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma, cutaneous basocellular carcinoma, and testicular  
5 seminoma.

12. A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at  
10 least one signal transduction inhibitor (STI) in a pharmaceutically acceptable carrier medium.

13. The pharmaceutical composition of claim 12, wherein said at least one STI is selected from the group  
15 consisting of bcr/abl kinase inhibitors, epidermal growth factor (EGF) receptor inhibitors, her-2/neu receptor inhibitors, farnesyl transferase inhibitors (FTIs), inhibitors of Akt family kinases or the Akt pathway, and cell cycle kinase inhibitors.

20 14. The pharmaceutical composition of claim 13, wherein said at least one STI is selected from the group consisting of STI 571, SSI-774, C225, ABX-EGF, trastuzumab, L-744,832, rapamycin, LY294002,  
25 flavopiridal, and UNC-01.

15. The pharmaceutical composition of claim 13, wherein said at least one STI is L-744,832.

30 16. The pharmaceutical composition of claim 12, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole

3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-  
diindolylmethane, indole-3-carbinol, 5-methyl-brassinin,  
epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-  
diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-  
5 tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp,  
propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-  
amino-2-naphthoic acid,  $\beta$ -carboline, 3-butyl- $\beta$ -carboline,  
6-fluoro-3-carbomethoxy- $\beta$ -carboline, 6-isothiocyanate-3-  
carbomethoxy- $\beta$ -carboline, 3-propoxy- $\beta$ -carboline, 3-  
10 carboxy- $\beta$ -carboline, 3-carbopropoxy- $\beta$ -carboline, and 3-  
carbo-tert-butoxy- $\beta$ -carboline.

17. The pharmaceutical composition of claim 12,  
wherein said at least one IDO inhibitor is  
15 1-methyl-tryptophan (1MT).

18. A method for treating a cancer in a patient in  
need thereof comprising administering to said patient,  
concurrently or sequentially, a therapeutically effective  
20 amount of at least one immunomodulator, other than IDO  
inhibitor, and an effective amount of at least one  
cytotoxic chemotherapeutic agent or at least one STI.

19. The method of claim 18, wherein said at least  
25 one immunomodulator is selected from the group consisting  
of CD40L, B7, B7RP1, ant-CD40, anti-CD38, anti-ICOS, 4-  
IBB ligand, dendritic cell cancer vaccine, IL2, IL12,  
IL1, IL18, ELC/CCL19, SLC/CCL21; MCP-1, IL-4, IL-18, TNF,  
IL-15, MDC, IFN $\alpha$ /b, M-CSF, IL-3, GM-CSF, IL-13, anti-IL-  
30 10, bacterial lipopolysaccharide (LPS), and poly CpG DNA.

20. The method of claim 18, wherein said at least  
one cytotoxic chemotherapeutic agent is selected from the  
group consisting of paclitaxel (Taxol®), cisplatin,

docetaxol, carboplatin, vincristine, vinblastine,  
methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil  
(5-FU), gemcitabine, estramustine, carmustine, adriamycin  
(doxorubicin), etoposide, arsenic trioxide, irinotecan,  
5 and epothilone derivatives.

21. The method of claim 18, wherein said at least  
one STI is selected from the group consisting of STI 571,  
SSI-774, C225, ABX-EGF, trastuzumab, L-744,832,  
10 rapamycin, LY294002, flavopiridal, and UNC-01.

22. A method for treating a chronic viral infection  
in a patient in need thereof comprising administering to  
said patient, concurrently or sequentially, a  
15 therapeutically effective amount of at least one  
indoleamine 2,3-dioxygenase (IDO) inhibitor and at least  
one chemotherapeutic agent.

23. The method of claim 22, wherein said at least  
20 one IDO inhibitor is selected from the group consisting  
of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-  
alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-  
tryptophan, indole 3-carbinol, 3,3'-diindolylmethane,  
brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-  
25 methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-  
indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-  
bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-  
DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp,  
brassilexin, 3-amino-2-naphthoic acid,  $\beta$ -carboline, 3-  
30 butyl- $\beta$ -carboline, 6-fluoro-3-carbomethoxy- $\beta$ -carboline,  
6-isothiocyanate-3-carbomethoxy- $\beta$ -carboline, and 3-  
propoxy- $\beta$ -carboline, 3-carboxy- $\beta$ -carboline, 3-  
carbopropoxy- $\beta$ -carboline, and 3-carbo-tert-butoxy- $\beta$ -  
carboline.

24. The method of claim 22, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

5           25. The method of claim 22, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU),  
10           gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

15           26. The method of claim 22, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered concurrently.

20           27. The method of claim 22, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered sequentially.

25           28. The method of claim 27, wherein said at least one IDO inhibitor is administered before said at least one chemotherapeutic agent.

          29. The method of claim 27, wherein said at least one chemotherapeutic agent is administered before said at least one IDO inhibitor.

30           30. The method of claim 22, wherein said chronic viral infection is selected from the group consisting of: hepatitis C virus (HCV), human papilloma virus (HPV), cytomegalovirus (CMV), Epstein-Barr virus (EBV),

varicella zoster virus, coxsackie virus, human immunodeficiency virus (HIV).

5 31. A pharmaceutical composition for the treatment of a chronic viral infection comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, at least one chemotherapeutic agent, and a pharmaceutically acceptable carrier medium.

10 32. The pharmaceutical composition of claim 31, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole  
15 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp,  
20 propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid,  $\beta$ -carboline, 3-butyl- $\beta$ -carboline, 6-fluoro-3-carbomethoxy- $\beta$ -carboline, 6-isothiocyanate-3-carbomethoxy- $\beta$ -carboline, 3-propoxy- $\beta$ -carboline, 3-carboxy- $\beta$ -carboline, 3-carbopropoxy- $\beta$ -carboline, and 3-  
25 carbo-tert-butoxy- $\beta$ -carboline.

33. The pharmaceutical composition of claim 32, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

30 34. The pharmaceutical composition of claim 31, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine,

vinblastine, methotrexate, cyclophosphamide, CPT-11, 5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

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35. A method for treating a cancer in a patient in need thereof comprising administering to said patient a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, wherein said IDO inhibitor selected from the group consisting of:  
10 phenyl-TH-DL-trp (3-(N-phenyl-thiohydantoin)-indole), propenyl-TH-DL-trp (3-(N-allyl-thiohydantoin)-indole), and methyl-TH-DL-trp (3-(N-methyl-thiohydantoin)-indole).

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36. The method of claim 35, wherein said cancer is selected from the group consisting of cancers of the prostate, colorectum, pancreas, cervix, stomach, endometrium, brain, liver, bladder, ovary, testis, head, neck, skin (including melanoma and basal carcinoma),  
20 mesothelial lining, white blood cell (including lymphoma and leukemia) esophagus, breast, muscle, connective tissue, lung (including small-cell lung carcinoma and non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma,  
25 cutaneous basocellular carcinoma, and testicular seminoma.

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37. A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor, wherein said IDO inhibitor selected from the group consisting of:  
phenyl-TH-DL-trp (3-(N-phenyl-thiohydantoin)-indole),  
propenyl-TH-DL-trp (3-(N-allyl-thiohydantoin)-indole),

and methyl-TH-DL-trp (3-(N-methyl-thiohydantoin)-indole);  
and a pharmaceutically acceptable carrier.

5           38. A method for treating a cancer in a patient in  
need thereof comprising administering to said patient,  
concurrently or sequentially, a therapeutically effective  
amount of at least one indoleamine 2,3-dioxygenase (IDO)  
inhibitor and at least one chemotherapeutic agent.

10           39. The method of claim 38, wherein said at least  
one chemotherapeutic agent is selected from the group  
consisting of paclitaxel (Taxol®), cisplatin, docetaxol,  
carboplatin, vincristine, vinblastine, methotrexate,  
cyclophosphamide, CPT-11, 5-fluorouracil (5-FU),  
15           gemcitabine, estramustine, carmustine, adriamycin  
(doxorubicin), etoposide, arsenic trioxide, irinotecan,  
and epothilone derivatives.

20           40. The method of claim 39, wherein said at least  
one chemotherapeutic agent is paclitaxel.

25           41. The method of claim 38, wherein said at least  
one IDO inhibitor is selected from the group consisting  
of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-  
alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-  
tryptophan, indole 3-carbinol, 3,3'-diindolylmethane,  
brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-  
methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-  
indoxyl 1,3-diacetate, 9-vinylcarbazole, acemetacin, 5-  
30           bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-  
DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp,  
brassilexin, 3-amino-2-naphthoic acid,  $\beta$ -carboline, 3-  
butyl- $\beta$ -carboline, 6-fluoro-3-carbomethoxy- $\beta$ -carboline,  
6-isothiocyanate-3-carbomethoxy- $\beta$ -carboline, 3-propoxy- $\beta$ -

carboline, 3-carboxy- $\beta$ -carboline, 3-carbopropoxy- $\beta$ -carboline, and 3-carbo-tert-butoxy- $\beta$ -carboline.

5        42. The method of claim 41, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).

10        43. The method of claim 38, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered concurrently.

44. The method of claim 38, wherein said at least one IDO inhibitor and said at least one chemotherapeutic agent are administered sequentially.

15        45. The method of claim 44, wherein said at least one IDO inhibitor is administered before said at least one chemotherapeutic agent.

20        46. The method of claim 44, wherein said at least one chemotherapeutic agent is administered before said at least one IDO inhibitor.

25        47. The method of claim 38, wherein said cancer is selected from the group consisting of cancers of the prostate, colorectum, pancreas, cervix, stomach, endometrium, brain, liver, bladder, ovary, testis, head, neck, skin (including melanoma and basal carcinoma), mesothelial lining, white blood cell (including lymphoma and leukemia) esophagus, breast, muscle, connective  
30        tissue, lung (including small-cell lung carcinoma and non-small-cell carcinoma), adrenal gland, thyroid, kidney, or bone; glioblastoma, mesothelioma, renal cell carcinoma, gastric carcinoma, sarcoma, choriocarcinoma,

cutaneous basocellular carcinoma, and testicular seminoma.

5           48. A pharmaceutical composition for the treatment of a cancer comprising an effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one chemotherapeutic agent in a pharmaceutically acceptable carrier medium.

10           49. The pharmaceutical composition of claim 48, wherein said at least one chemotherapeutic agent is selected from the group consisting of paclitaxel (Taxol®), cisplatin, docetaxol, carboplatin, vincristine, vinblastine, methotrexate, cyclophosphamide, CPT-11,  
15           5-fluorouracil (5-FU), gemcitabine, estramustine, carmustine, adriamycin (doxorubicin), etoposide, arsenic trioxide, irinotecan, and epothilone derivatives.

20           50. The pharmaceutical composition of claim 49, wherein said at least one STI is paclitaxel.

25           51. The pharmaceutical composition of claim 48, wherein said at least one inhibitor of IDO is selected from the group consisting of 1-methyl-DL-tryptophan (1MT),  $\beta$ -(3-benzofuranyl)-DL-alanine, beta-(3-benzo(b)thienyl)-DL-alanine, 6-nitro-L-tryptophan, indole 3-carbinol, 3,3'-diindolylmethane, brassinin, 3,3'-diindolylmethane, indole-3-carbinol, 5-methyl-brassinin, epigallocatechin gallate, 5-Br-4-Cl-indoxyl 1,3-  
30           diacetate, 9-vinylcarbazole, acemetacin, 5-bromo-DL-tryptophan, 5-bromoindoxyl diacetate, phenyl-TH-DL-trp, propenyl-TH-DL-trp, methyl-TH-DL-trp, brassilexin, 3-amino-2-naphthoic acid,  $\beta$ -carboline, 3-butyl- $\beta$ -carboline, 6-fluoro-3-carbomethoxy- $\beta$ -carboline, 6-isothiocyanate-3-

carbomethoxy- $\beta$ -carboline, 3-propoxy- $\beta$ -carboline, 3-carboxy- $\beta$ -carboline, 3-carbopropoxy- $\beta$ -carboline, and 3-carbo-tert-butoxy- $\beta$ -carboline.

- 5           52. The pharmaceutical composition of claim 48, wherein said at least one IDO inhibitor is 1-methyl-tryptophan (1MT).